UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	SACV 15-00366 JVS (JCGx)	Date	August 10, 2015
Title	Austin Seedman v. Cochlear Americas, et al.		

Present: The Honorable	James V. Selna

Karla J. Tunis	Sharon Seffens
Deputy Clerk	Court Reporter
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
Michael Sutton	Michael Maddigan Laura Schultz Colton

Proceedings: **Defendant Cochlear Ltd.'s Motion to Dismiss for Lack of Jurisdiction (fld 6-18-15)**

Defendant Cochlear Americas' Motion to Dismiss Pursuant to FRCivP 12(b)(6) (fld 6-22-15)

Cause called and counsel make their appearances. The Court's tentative ruling is issued. Counsel make their arguments. The Court STAYS the Defendant Cochlear Ltd.'s Motion to Dismiss for Lack of Jurisdiction for forty-five (45) days pending completion of jurisdictional discovery as directed below**. The Court directs that the plaintiff file his supplemental opposition to the motion to dismiss for lack of jurisdiction not later than September 25, 2015 and defendants may file any response to the opposition by October 2, 2015.**

The Court GRANTS IN PART and DENIES IN PART Defendant Cochlear Americas' Motion to Dismiss Pursuant to FRCivP 12(b)(6).

The Court makes these ruling in accordance with the tentative ruling as follows:

Before the Court are two motions.

Pursuant to Federal Rule of Civil Procedure 12(b)(2), Defendant Cochlear Limited ("CLTD") moves to dismiss Plaintiff Austin Seedman's ("Seedman") Complaint for lack of personal jurisdiction. (Docket No. 16.) Seedman opposes. (Docket No. 18.) CLTD has replied. (Docket No. 20.)

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. SACV 15-00366 JVS (JCGx) Date August 10, 2015

Title Austin Seedman v. Cochlear Americas, et al.

Pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendant Cochlear Americas Corporation ("CAM") moves to dismiss Seedman's Complaint for failure to state a claim. (Docket No. 17.) Seedman opposes. (Docket No. 19.) CAM has replied. (Docket No. 26.)

As described herein, the Court STAYS CLTD's motion to dismiss for lack of jurisdiction pending additional limited jurisdictional discovery. The Court GRANTS IN PART and DENIES IN PART CAM's motion to dismiss for failure to state a claim.

I. BACKGROUND

Unless otherwise noted, the following facts are alleged in Seedman's Complaint. (See Docket No. 1.) CLTD is an Australian public company with its principal place of business in New South Wales, Australia. (Compl. ¶ 17.) CLTD is a manufacturer of implantable medical hearing devices. (Mem. Supp. 12(b)(2) Mot. Dismiss 1.) CAM is an Delaware corporation with its principal place of business in Colorado. (Compl. ¶ 16.) CAM is a wholly-owned subsidiary of CLTD. (Id.) CLTD and CAM manufacture, distribute, and sell the Cochlear Nucleus C1512 cochlear implant medical device. (Id. ¶ 1.)

Seedman had a Cochlear Nucleus CI512 cochlear implant medical device (the "cochlear implant") surgically implanted into his left ear in June 2011. (Id. ¶ 1, 49.) The cochlear implant at issue was subject to a global recall in September 2011 due to increase in the number of implant failures. (Id. ¶ 2, 41.)

In March 2013, Seedman's cochlear implant failed, allegedly "due to an electronic failure caused by a loss of hermeticity (i.e. failure of the moisture impervious seal)." (Id. ¶ 50, 56.) Seedman alleges that the loss of hermeticity resulting in the cochlear implant's failure was a result of unintended variations in the "brazing process" during the implant's manufacture. (Id. ¶ 57.)

Based on the foregoing, Seedman filed this action on March 3, 2015. (Docket No. 1.) Seedman asserts the following claims against CLTD and CAM: (1) strict liability based on a manufacturing defect, design defect, and/or failure to warn; (2) negligence; (3) negligent misrepresentation; (4) breach of express warranty; and (5) breach of implied

warranty of merchantability. (Id.)

II. CLTD'S 12(b)(2) MOTION TO DISMISS

CLTD argues that it is not subject to personal jurisdiction in this Court, and thus the claims against it should be dismissed. (Mem. Supp. 12(b)(2) Mot. Dismiss. 1-2.)

A. Legal Standard

Personal jurisdiction refers to a court's power to render a valid and enforceable judgment against a particular defendant. See World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 291 (1980); Pennoyer v. Neff, 95 U.S. 714, 720 (1877), overruled in part by Shaffer v. Heitner, 433 U.S. 186, 206 (1977). The contours of that power are shaped, in large part, by the Due Process Clause of the Fourteenth Amendment, which requires sufficient "contacts, ties, or relations" between the defendant and the forum state before "mak[ing] binding a judgment *in personam* against an individual or corporate defendant." Int'l Shoe Co. v. Washington, 326 U.S. 310, 319 (1945). Due Process requires that "there exist 'minimum contacts' between the defendant and the forum" in order to protect the defendant "against the burdens of litigating in a distant or inconvenient" court and lend "a degree of predictability to the legal system." World-Wide Volkswagen, 444 U.S. at 291, 292, 297.

Jurisdiction must also comport with law of the forum state. See Fed. R. Civ. P. 4(k)(1)(A); Yahoo! Inc. v. La Ligue Contre Le Racisme Et L'Antisemitisme, 433 F.3d 1199, 1205 (9th Cir. 2006) (en banc). Because California's long-arm statute allows the exercise of jurisdiction on any basis consistent with the state and federal constitutions, the jurisdictional analyses of state law and federal due process are the same. Cal. Code. Civ. Proc. § 410.10; see also Yahoo!, 433 F.3d at 1205.

"Where a defendant moves to dismiss a complaint for lack of personal jurisdiction, the plaintiff bears the burden of demonstrating that jurisdiction is appropriate." Schwarzenegger v. Fred Martin Motor Co., 374 F.3d 797, 800 (9th Cir. 2004). Plaintiff's allegations of jurisdictional facts must also be supported by competent proof. Hertz Corp. v. Friend, 559 U.S. 77, 96-97 (2010). In the absence of an evidentiary hearing, "[h]owever, this demonstration requires that the plaintiff 'make only a prima facie

showing of jurisdictional facts to withstand the motion to dismiss.'" Pebble Beach Co. v. Caddy, 453 F.3d 1151, 1154 (9th Cir. 2006) (quoting Doe v. Unocal Corp., 248 F.3d 915, 922 (9th Cir. 2001)). To make the requisite showing, a plaintiff "need only demonstrate facts that if true would support jurisdiction over the defendant." Harris Rutsky & Co. Ins. Servs., Inc. v. Bell & Clements Ltd., 328 F.3d 1122, 1129 (9th Cir. 2003) (internal quotation marks and citation omitted). In evaluating the plaintiff's showing, all uncontroverted allegations in the complaint are taken as true and all disputed facts are resolved in plaintiff's favor. Id.; Schwarzenegger, 374 F.3d at 800.

Personal jurisdiction may be premised on general personal jurisdiction (based on a defendant's continuous presence in a state) or specific personal jurisdiction (based on specific contacts with the state specifically related to the claims at issue).

1. General Personal Jurisdiction

For general jurisdiction to exist over a nonresident defendant, it must have affiliations with the forum state "so continuous and systematic as to render the foreign corporation essentially at home in the forum State." Daimler AG v. Bauman, __ U.S. __, 134 S.Ct. 746, 758 n.11 (2014) (quoting Goodyear Dunlop Tires Operations, S.A. v. Brown, 564 U.S. __, 131 S.Ct. 2846, 2851 (2011)) (internal quotation marks omitted). In other words, a defendant's "continuous and systematic general business contacts" with the forum must "approximate physical presence" in the forum state. Schwarzenegger, 374 F.3d at 801 (quoting Helicopteros Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 416 (1984) and Bancroft & Masters, Inc. v. Augusta Nat'l, Inc., 223 F.3d 1082, 1086 (9th Cir. 2000)).

A nonresident defendant's "continuous activity of some sorts within a state," however, is not enough by itself to support exercise of general jurisdiction. Goodyear, 131 S.Ct. at 2856. "Unless a defendant's contacts with a forum are so substantial, continuous, and systematic that the defendant can be deemed to be 'present' in that forum for all purposes," a forum may not exercise general jurisdiction. Yahoo!, 433 F.3d at 1205. Where general jurisdiction exists, the Court has jurisdiction over the defendant for all purposes, even in cases where the claims arise from dealings unrelated to those that establish jurisdiction. Daimler, 134 S.Ct. at 754.

2. Specific Personal Jurisdiction

A defendant is subject to specific personal jurisdiction only if a controversy arises out of or is sufficiently related to the defendant's contacts with the forum state. Goodyear, 131 S. Ct. at 2851, see also Omeluk v. Langsten Slip & Batbyggeri A/S, 52 F.3d 267, 270 (9th Cir. 1995). The Court of Appeals for the Ninth Circuit employs a three-part test to determine whether a court possesses specific jurisdiction over a particular defendant: (1) the defendant must have "performed some act or consummated some transaction within the forum or otherwise purposefully availed himself of the privileges of conducting activities in the forum"; (2) the claim must "arise[] out of or result[] from the defendant's forum-related activities"; and (3) the exercise of jurisdiction must be reasonable. Pebble Beach, 453 F.3d at 1155.

The plaintiff bears the burden on the first two prongs. Schwarzenegger, 374 F.3d at 802. If the plaintiff fails to satisfy either prong, "jurisdiction in the forum would deprive the defendant of due process of law." See Omeluk, 52 F.3d at 270. "If the plaintiff succeeds in satisfying both of the first two prongs, the burden then shifts to the defendant to 'present a compelling case' that the exercise of jurisdiction would not be reasonable." Schwarzenegger, 374 F.3d at 802 (quoting Burger King Corp. v. Rudzewicz, 471 U.S. 462, 476-78 (1985)).

B. Discussion

CLTD argues that it is not subject to either general or specific personal jurisdiction in this Court. (Mem. Supp. 12(b)(2) Mot. Dismiss 5-17.) Seedman maintains that the Court has both general and specific jurisdiction over CLTD. (Opp'n 12(b)(2) Mot. Dismiss 5-13.)

1. Jurisdictional Facts

As noted above, CLTD is an Australian public company with its principal place of business in New South Wales, Australia. (Mem. Supp. 12(b)(2) Mot. Dismiss 2.) CLTD has no offices, manufacturing plants, bank accounts, employees, or commercial agents in California. (York Decl. ¶¶ 5-7, Docket No. 16-2.) It is not registered to do business in California, has no registered agent in California, and does not pay California income tax.

(York ¶ 11.) CAM, however, is registered to do business in California. (Sutton Decl. ¶ 9, Docket No. 18-1.)

CLTD does not manufacture, distribute, or sell any products in California. (York Decl. ¶ 10.) Instead, CLTD sells products to CAM, which exclusively sells and distributes the products in the United States. (York Decl. ¶ 10.) CAM is exclusively responsible for advertising CLTD products in the United States and deciding where they should be marketed. (York Decl. ¶¶ 9, 19.)

CLTD maintains that it and CAM are separate legal entities. (York Decl. ¶ 12.) CLTD and CAM file separate tax returns, prepare separate financial statements, maintain separate corporate books and records, and maintain separate and distinct accounting, human resources, information technology, legal and other administrative departments. (York Decl. ¶¶ 12, 13, 18.) CLTD and CAM have no common bank accounts, no common officers, and only one common director. (York Decl. ¶¶ 14, 15.)

2. General Jurisdiction

CLTD challenges the Court exercise of general personal jurisdiction over it. (Mem. Supp. 12(b)(2) Mot. Dismiss 6-8.) Specifically, CLTD argues that it does not engage in continuous, systematic general business in California such that it is rightfully considered "at home" here for the purposes of establishing general personal jurisdiction. (Id.)

Seedman argues that the Court has general jurisdiction over CLTD based on an "alter ego" theory of general jurisdiction. (Opp'n Mot. Dismiss 10-14.) "[T]he alter ego test may be used to extend personal jurisdiction to a foreign parent or subsidiary when, in actuality, the foreign entity is not really separate from its domestic affiliate." Ranza v. Nike, Inc., __ F.3d __, No. 13-35251, 2015 WL 4282986, at *8 (9th Cir. July 16, 2015). In order to satisfy the alter ego test, a plaintiff must make a prima facie case that (1) "there is such unity of interest and ownership that the separate personalities of the two entities no longer exist;" and (2) "failure to disregard their separate identities would result in fraud or injustice." Id. at *9 (quoting Doe v. Unocal, 248 F.3d 915, 926 (9th Cir. 2001)).

The Court does not find that Seedman has made a prima facie case of an alter ego relationship between CLTD and CAM. Seedman cannot meet the "unity of interest and ownership" prong when the evidence shows that each entity "observes all of the corporate formalities necessary to maintain corporate separateness," even if it is able to show that CLTD is actively involved in decisionmaking about CAM. See Ranza, 2015 WL 4282986, at *9 (quoting Unocal, 248 F.3d at 928.) Although Seedman argues that CLTD's annual report discloses its control and supervision of CAM's operations (Opp'n 12(b)(2) Mot. Dismiss 11-12), Seedman does not refute CLTD's proof that both entities observe their respective corporate formalities. (See Reply 8-9.)

Because Seedman has not made a prima facie case for exercise of general personal jurisdiction based on an alter ego theory, and because Seedman makes no other arguments supporting general jurisdiction, the Court concludes that Seedman has not met his burden of showing that general jurisdiction exists.

3. Specific Jurisdiction

CLTD also challenges the Court exercise of specific personal jurisdiction over it. (Mem. Supp. 12(b)(2) Mot. Dismiss 8-13.) Specifically, CLTD argues that it neither transacted business with Seedman in California nor "purposefully availed" itself towards California. (Id. at 9-13.)

Seedman alleges that the Court has jurisdiction over CLTD and CAM based on (1) their transaction of business with Seedman in California; (2) their supply of goods to Seedman in California; and (3) their commission of a tortious act causing injury to Seedman in California. (FAC ¶ 29.) Seedman argues that CLTD's use of CAM as a distributor for CLTD products in California and CLTD's maintenance of a website that allows consumers to find California clinics that implant CLTD devices indicate that CLTD purposefully availed itself to California. (Opp'n Mot. Dismiss 7.) Seedman argues that CLTD purposefully availed itself to California under the "effects" test of Calder v. Jones, 465 U.S. 783 (1984) (Opp'n 12(b)(2) Mot. Dismiss 6.)

However, CLTD correctly notes that the Calder "effects" test only applies to certain intentional torts and thus is inapposite here. (Reply 9-10, 10 n. 41, citing Holland Am. Line. Inc. v. Wartsila N. Am., Inc., 485 F.3d 450, 460 (9th Cir. 2007)). CLTD

supposes that Seedman intended to argue that the Court had specific jurisdiction over CLTD under the "stream of commerce" theory of jurisdiction. (Reply 10.) CLTD argues that even under the "stream of commerce" theory, it did not purposefully avail itself to California. (Id.)

"The placement of a product into the stream of commerce, without more, is not an act purposefully directed toward a forum state." Holland Am. Line Inc. v. Wartsila N. Am., Inc., 485 F.3d 450, 459 (9th Cir. 2007). For example, a foreign manufacturer is not subjected to the specific jurisdiction of a forum state merely based on the sales of its distributors. J. McIntyre Machinery, Ltd. v. Nicastro, 131 S. Ct. 2780 (2011) (foreign manufacturer not subject to jurisdiction of forum state where distributor agreed to sell manufacturer's machines in United States, and manufacturer had no presence in state, did not advertise there, or send any employees there). Seedman does not point to what "more" CLTD did to target its products to California. It conducts no manufacturing, marketing, or selling of products in California, and its distributor CAM markets and sells the products entirely on its own. Cf. Falco v. Nissan N. Am. Inc., __ F. Supp. 3d __, Case No. CV 13-00686 DDP (MANx), 2015 WL 1534800 (C.D. Cal. April 6, 2015) (personal jurisdiction existed over foreign manufacturer where foreign manufacturer directly advertised in forum state, worked closely with domestic distributor/subsidiary to distribute, sell, and service products, and intended products at issue to be sold in forum state). However, as the Court discusses infra Part II.B.4, additional discovery is needed to fully ascertain the degree to which CLTD purposefully availed itself to California through its relationship with its exclusive distributor and subsidiary CAM.

Seedman also argues that CLTD's website provides a basis for personal jurisdiction over CLTD because it allows users to identify clinics where CLTD products are offered in California. (Opp'n 12(b)(2) Mot. Dismiss.) The Court disagrees.

The Ninth Circuit has developed a framework for analyzing whether a defendant's maintenance of a website constitutes purposeful availment towards a forum state. Cybersell, Inc. v. Cybersell, Inc., 130 F.3d 414 (9th Cir. 1997). A passive website, which establishes a "mere web presence," does not establish jurisdiction by itself. Holland, 485 F.3d at 460; Cybersell, 130 F.3d 414 at 417-418 (discussing Bensusan Rest. Corp. v. King, 937 F. Supp. 295 (S.D.N.Y. 1996), aff'd 126 F.3d 25 (2d Cir. 1997) (general access web page that did not sell concert tickets but rather directed browsers to names

and addresses of ticket sellers did not provide minimum contacts with forum state)).

On the other hand, an "interactive" website may provide sufficient contacts depending on the "level of interactivity and commercial nature of the exchange of information" that occurs on the website. Cybersell, 130 F.3d at 418. "If a website falls somewhere between passive and interactive, 'the likelihood that personal jurisdiction can be constitutionally exercised is directly proportionate to the nature and quality of commercial activity that an entity conducts over the internet.'" Quigley v. Guvera IP Pty Ltd., No. C 10-03569 CRB, 2010 WL 5300867 (N.D. Cal. 2010) (finding website interactive and commercial when it required users to register in order to download free music because registration information was used to generate targeted advertising revenue; quoting Cybersell, 130 F.3d at 418).

Here, CLTD's website cannot serve as minimum contacts with California. CLTD sells no products on its website. (Narayanan Decl. ¶ 6.) The website initially directs users to select the page of the appropriate regional subsidiary (in this case, CAM's website for "United States & Canada"). (Id. ¶¶ 3-5.) And while it appears that users can use an interactive "Find your nearest clinic" feature directly from the international CLTD website, this single interactive feature is not sufficient to confer jurisdiction. The clinic location feature merely provides a user with the name, address, and telephone numbers of nearby clinics that offer CLTD cochlear implants. The feature does not require a user to give CLTD any commercially valuable information and is functionally no different from a website that merely lists the contact information for stores where its products can be purchased.

4. Seedman's Request for Jurisdictional Discovery

In the event that the Court concludes that Seedman has not made a prima facie showing of jurisdiction, Seedman requests that the Court permit the parties to conduct limited jurisdictional discovery. (Opp'n 12(b)(6) Mot. Dismiss 14-15.) CLTD opposes. (Reply Supp. 12(b)(6) Mot. Dismiss. 13-14.)

Jurisdictional discovery "may be appropriately granted where pertinent facts bearing on the question of jurisdiction are controverted or where a more satisfactory showing of the facts is necessary." Boschetto v. Hansing, 539 F.3d 1011, 1020 (9th Cir.

2008). Here, the Court finds that limited jurisdictional discovery could yield additional facts about the relationship between CLTD and CAM, which could establish specific jurisdiction over CLTD in this case. Without limited jurisdictional discovery, the Court is presented with only CLTD's perspective of the CLTD-CAM relationship. Furthermore, limited jurisdictional discovery supplied key jurisdictional facts for a court's exercise of specific jurisdiction of a foreign defendant manufacturer in a similar case, Falco v. Nissan North America Inc., __ F. Supp. 3d __, Case No. CV 13-00686 DDP (MANx) 2015 WL 1534800 (C.D. Cal. April 6, 2015).

Accordingly, the Court grants Seedman's request for limited jurisdictional discovery.

III. CAM'S 12(b)(6) MOTION TO DISMISS

A. Legal Standard

Under Rule 12(b)(6), a defendant may move to dismiss for failure to state a claim upon which relief can be granted. A plaintiff must state "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). A claim has "facial plausibility" if the plaintiff pleads facts that "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

In resolving a 12(b)(6) motion under Twombly, the Court must follow a two-pronged approach. First, the Court must accept all well-pleaded factual allegations as true, but "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 556 U.S. at 678. Nor must the Court "'accept as true a legal conclusion couched as a factual allegation.'" Id. at 678-80 (quoting Twombly, 550 U.S. at 555). Second, assuming the veracity of well-pleaded factual allegations, the Court must "determine whether they plausibly give rise to an entitlement to relief." Id. at 679. This determination is context-specific, requiring the Court to draw on its experience and common sense, but there is no plausibility "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct." Id.

B. Discussion

CAM primarily argues that Seedman's claims are preempted by the Medical Devices Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). (Mem. Supp. 12(b)(6) Mot. Dismiss 7–10.) CAM additionally argues that some of Seedman's claims are impliedly preempted or that Seedman's conclusory allegations fail to satisfy Twombly/Iqbal requirements. (Id. at 14–16.) Therefore, the Court briefly reviews the framework for MDA preemption before analyzing the merits of Seedman's individual claims.

1. Preemption[1]

The MDA gives the Food and Drug Administration ("FDA") authority over medical devices and authorizes the FDA to issue implementing regulations. Tansey v. Cochlear Ltd., No. 13-CV-4628 SJF, 2014 WL 4829453, at *6 (E.D.N.Y. Sept. 26, 2014) (internal quotation marks and citation omitted). Under the MDA, medical device manufacturers must register each device with the FDA prior to manufacture of that device so that the FDA can classify each device according to the "level of regulatory control necessary to provide for the device's safety and effectiveness." Id. (citing 21 U.S.C. § 360c). "Medical devices are classified by three (3) categories based on the risk they pose to the public," with Class III devices being the "most heavily regulated and must pass premarket approval ["PMA"]." Tansey, 2014 WL 4829453, at *6 (quoting Medtronic v. Lohr, 518 U.S. 470, 477 (1996)). The parties do not dispute that the cochlear implant is a Class III medical device. (See Mem. Supp. 12(b)(6) Mot. Dismiss 5:4–5; Compl. ¶ 64.)

With respect to medical devices, the MDA's preemption language provides the following:

[1] Two recent federal district court cases throughly review the legal framework for MDA preemption in cases involving the same defendants here and plaintiffs alleging similar claims to those of Seedman. See Thibodeau v. Cochlear Ltd., No. CV-13-02184-PHX-DGC, 2014 WL 3700868, at *1 (D. Ariz. July 25, 2014); Tansey v. Cochlear Ltd., No. 13-CV-4628 (SJF), 2014 WL 4829453, at *1 (E.D.N.Y. Sept. 26, 2014). The Court thus borrows significantly from Thibodeau and Tansey when describing the legal framework for MDA preemption.

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k.[2] The Ninth Circuit noted that "[a] trio of Supreme Court cases address preemption under the MDA." Perez v. Nidek Co., 711 F.3d 1109, 1117 (9th Cir. 2013); see Medtronic v. Lohr, 518 U.S. 470, 475 (1996); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001); Riegel v. Medtronic, Inc., 552 U.S. 312, 315 (2008). From these three cases, the Ninth Circuit concluded that the "rule that emerges from these cases is that the MDA *does not* preempt a state-law claim for violating a state-law duty that *parallels a federal-law duty* under the MDA." Stengel v. Medtronic, Inc., 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc) (italics supplied). However, the U.S. Supreme Court has also described the circumstances in which the MDA does preempt a state-law claim.

Buckman addresses implied preemption under the MDA. Perez, 711 F.3d at 1117. The Supreme Court reasoned that "claims that a device manufacturer had made fraudulent representations to the FDA were 'inherently federal in nature' because the relationship between the manufacturer and the FDA 'originates from, is governed by, and terminates according to federal law.'" Id. (citing Buckman, 531 U.S. at 347–48). Thus, the Supreme Court held that "fraud-on-the-FDA" claims were impliedly preempted. Id.

Lohr and Riegel address the MDA's express preemption provision. Perez, 711 F.3d at 1117. Lohr first announced the rule that § 360k does not preempt state-law claims that "parallel" federal requirements. Lohr, 518 U.S. at 495; see also Riegel, 552 U.S. at 330 ("Thus, § 360 does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations . . . ."). However, Riegel addressed whether § 360k "bars common-law claims challenging the safety and effectiveness of a medical device given [PMA] by the [FDA]." Id. at 315. To determine whether § 360k

[2] For the remainder of this Order, the Court will simply refer to this section as "§ 360k."

preempts state-law claims, Riegel established a two-part test that requires courts to determine "(1) whether the federal government established 'requirements' applicable to the device in question, and, if so, (2) whether the state common law claims are based on state law requirements 'that are different from, or in addition to the federal ones' and 'relate to safety and effectiveness.'" Thibodeau v. Cochlear Ltd., No. CV-13-02184-PHX-DGC, 2014 WL 3700868, at *2 (D. Ariz. July 25, 2014) (citing Riegel, 552 U.S. at 321–22.). Thus, state-law claims are preempted if they "impose state requirements that differed from, or added to, the PMA-approved standards." Tansey, 2014 WL 4829453, at *7 (internal quotation marks and citation omitted).

"Together, express preemption and implied preemption leave only a 'narrow gap' through which the plaintiff's claims must fit in order to survive." Kashani Matts v. Medtronic, Inc., No. SACV 13-01161-CJC(RNBx), 2014 WL 819392, at *2 (C.D. Cal. Feb. 14, 2014) (citing Perez, 711 F.3d at 1120).

2. Claim-by-Claim Analysis

Seedman "does not challenge the FDA's approval of the design, manufacturing process, or labeling of a premarket approved medical device." (Compl. ¶ 11.) Similar to the plaintiff in Thibodeau, Seedman also does not dispute that the first step of the Riegel test is met here; namely, that the federal government has established requirements applicable to the cochlear implant. (Id.; Mem. Supp. 12(b)(6) Mot. Dismiss 2–3); Thibodeau, 2014 WL 3700868, at *3. Instead, also similar to the plaintiff in Thibodeau, Seedman argues that his state-law claims are based on duties "parallel" to federal law duties, and thus "do not impose requirements different from, or in addition to, those imposed by federal law." See id.; (Opp'n 12(b)(6) Mot. Dismiss 2.)

The Court addresses each claim in turn, in accordance with the second step of Riegel, to determine whether they are "parallel" claims or whether they are expressly or impliedly preempted by the MDA.

a. *First Claim: Strict Liability Defective Manufacturing*

Seedman's first claim alleges that CAM is strictly liable for manufacturing defects in his cochlear implant. (Compl. ¶87–92.) More specifically, the manufacturing defect

that Seedman alleges is the failure of the moisture impervious seal in the cochlear implant. (Id. at ¶¶ 56, 75–80.) This allegedly resulted from unintended variations in the brazing, or metal-joining manufacturing, process that made the cochlear implant more susceptible to developing microcracks. (Id.) Similar to the plaintiff in Tansey, Seedman alleges that his cochlear implant "deviated in a material way from [CAM's] approved product manufacturing specifications, PMA manufacturing specifications, current good manufacturing practices ('CGMP') and/or other applicable federal law, causing an unreasonably dangerous risk of hermeticity and related device failures which required [Seedman] to under go additional medical treatment to remove and replace the [cochlear] implant." Tansey, 2014 WL 4829453, at *10; (Id. at ¶¶ 80–86.)

In particular, Seedman points to three federal requirements that CAM allegedly failed to abide by in the manufacturing process of the cochlear implant. One is 21 U.S.C. § 351(h), which provides, in part, that a device "shall be deemed to be adulterated" when "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements" in CGMP regulations. See also 21 U.S.C. § 360j(f)(1) (referred to in § 351(h) because it provides authority for the promulgation of CGMP regulations). Generally applicable to various medical devices, the CGMP requires each manufacturer to "develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications." 21 C.F.R. § 820.70(a).[3] Consequently, medical device manufacturers are required to "establish and maintain procedures for validating the device design," which includes "testing of production units under actual or simulated use conditions." 21 C.F.R. § 820.30(g). In sum, Seedman alleges that CAM's failure during manufacturing to validate the design through testing of the cochlear implant under actual or simulated use conditions renders the cochlear implant "adulterated." (Compl. ¶¶ 70–85.)

Similar to the plaintiff's claim in Tansey, Seedman is not alleging that the cochlear implant "require[s] different manufacturing from that approved by the FDA." Tansey, 2014 WL 4829453, at *10. Rather, Seedman alleges that CAM's manufacturing process

[3] At oral argument, CAM contended that Seedman did not specifically cite this regulation in his Complaint. The Court agrees that it was not specifically enumerated in the Complaint, but Seedman alleges that CAM failed to maintain the CGMP in accordance with "21 C.F.R. § 820 et seq." (Compl. ¶ 83.) The "et seq." abbreviation in paragraph 83 sufficiently encompasses § 820.70(a).

of the cochlear implant "deviated from the FDA approved plan and specifications and that the deviation, i.e., the breach of hermeticity, was the cause of plaintiff's injury." Id.; (Compl. ¶¶ 70–85, 87–92.) Thus, even though Seedman's claim relates to "safety and effectiveness," it is not "different from, or in addition to" the federal requirements. See Riegel, 552 U.S. at 321–22. Rather, his state-law claim parallels the federal requirements previously discussed.

However, CAM additionally argues that Seedman's claims are conclusory. At oral argument, CAM asserted that to meet the Twombly/Iqbal requirements, Seedman's Complaint must specify which process or part of the cochlear implant's design failed to be validated during the manufacturing process. CAM further contended that Seedman's Complaint is more identical to the complaint in Thibodeau than that in Tansey. The Court has reviewed the complaints in both Thibodeau and Tansey,[4] and agrees that the allegations in Seedman's Complaint are nearly identical to those in Thibodeau. (Compare Compl. ¶¶ 64–85 with Thibodeau Compl. ¶¶ 92–114.) Similar to the plaintiff in Thibodeau, Seedman's Complaint lists thirty PMA or federal standards that CAM allegedly failed to follow. (Id. at ¶ 85); Thibodeau, 2014 WL 3700868, at *3. The Thibodeau Complaint also alleges that CAM violated 21 C.F.R. § 820.30(g) by failing to perform the design validation during the manufacturing process. (Thibodeau Compl. ¶ 101.) But the similarities between Seedman's Complaint and the Thibodeau Complaint do not automatically warrant dismissal here. As an out-of-state federal district court case, Thibodeau is only persuasive authority.

Moreover, CAM's argument ignores the fact that the Tansey Complaint, which met the Twombly/Iqbal requirements, also contains many of the same allegations as those in Seedman's Complaint. (Compare Compl. ¶¶ 64–85 with Tansey Complaint ¶¶ 83, 97–109.) Although Tansey is slightly less persuasive authority than Thibodeau because it is from a district court outside of the Ninth Circuit, this point is negligible. Tansey,

[4] The Court takes judicial notice of the complaints in these two cases. (See Compl., Dkt. No. 1, No. CV-13-02184-PHX-DGC (hereinafter, the "Thibodeau Complaint"); Compl., Dkt. No. 1, No. 13-CV-4628 (SJF) (hereinafter, the "Tansey Complaint").) Courts "may take [judicial] notice of proceedings in other courts, both within and without the federal judicial system, if those proceedings have a direct relation to matters at issue." Bias v. Monynihan, 508 F.3d 1212, 1225 (9th Cir. 2007) (internal citations and quotation marks omitted); Fed. R. Evid. 201(b).

Thibodeau, and this case all involve applying federal pleading requirements in the context of federal preemption. This Court simply agrees more with the conclusion regarding this claim that is reached in Tansey than the one reached in Thibodeau. Compare Tansey, 2014 WL 4829453, at *10 ("[T]he allegations comply with the standards in Twombly and Iqbal.") with Thibodeau, 2014 WL 3700868, at *3 ("Although these allegations attempt to follow the form of parallel state claims, they are wholly conclusory. They include virtually no facts.").

In contrast to Thibodeau and CAM, the Court concludes that Seedman's allegations include specific factual allegations regarding what allegedly went wrong in the cochlear implant's manufacturing process. According to Seedman's allegations, which the Court must accept as true in this stage of the litigation, the FDA issued a recall of the cochlear implants in October 2011 because approximately two percent of the implants had experienced a loss of hermeticity. (Compl. ¶¶ 43, 46.) CAM's testing of Seedman's implant revealed that it failed because of a loss of hermeticity. (Id. at ¶ 53.) The loss of hermeticity resulted from "unintended variations in the brazing process," which is the "metal-joining manufacturing process that joined the feedthrough of the Cochlear Implant to the receiver/stimulator's titanium chassis." (Id. at ¶¶ 76–77.) The unintended variations made the implant more susceptible to microcracks in the braze joint, thereby increasing the risk of hermeticity failure. (Id. at ¶¶ 78–79.) If CAM had performed the required testing, or design validation, of the cochlear implants, then it would have uncovered these "unintended variations" in the manufacturing process. (Id. at ¶ 73.) At this stage in the litigation, the Court cannot ignore these sufficient allegations and accept CAM's assumption that Seedman's failed implant resulted from a random error in the manufacturing process.

Moreover, "[t]he elements of a strict products liability cause of action are a defect in the manufacture . . . causation, and injury." Cnty. of Santa Clara v. Atl. Richfield Co., 137 Cal. App. 4th 292, 318 (2006). Seedman pleads sufficient facts to meet these elements. (See Compl. ¶¶ 72–92.)

Because Seedman's claim is parallel to federal requirements and alleges sufficient facts to meet the Twombly/Iqbal requirements, his manufacturing defect claim survives.

b. *Second Claim: Strict Liability Defective Design*

Seedman's second claim alleges that CAM's cochlear implant was "defective in design or formulation." (Compl. ¶ 95.) Similar to his manufacturing defect claim, Seedman alleges that the design defect caused the loss of hermeticity, or the failure of the moisture impervious seal, in the cochlear implant. (Id. at ¶¶ 71–86.) However, Seedman's allegations "establish that the breach of hermeticity resulted from the manufacturing processes and not because [CAM] allegedly deviated from the PMA approved design." Tansey, 2014 WL 4829453, at *12. The allegations that CAM failed to validate the cochlear implant's design during the manufacturing process provide the basis for a valid manufacturing defect claim, but not for a valid design defect claim. Without any other basis for his design defect claim, Seedman's allegations appear to only "challenge the PMA approval of the design" for the cochlear implant. Id. at *11. Thus, the MDA preempts this claim. Id.; see also Thibodeau, 2014 WL 3700868, at *4 ("Plaintiff has not pled facts supporting the allegation that the design of his [cochlear implant] was different than that approved in the PMA.")

b. *Third Claim: Strict Liability Failure to Warn*

Seedman alleges that CAM "breached [its] duty of care under applicable state law" when CAM "failed to report to the FDA of the information [CAM] received regarding the increasing number of hermeticity failures" with the cochlear implant that "caused or contributed to serious injury." (Compl. ¶¶ 74, 102–03.) This failure to warn allegedly violates 21 C.F.R § 803.50(a) and 21 U.S.C. § 360i(a). (Id. at ¶ 74.)

In California, manufacturers are strictly liable for injuries caused by their failure to give warning of dangers that were known to the specific community at the time they manufactured and distributed the product. Carlin v. Superior Court, 13 Cal. 4th 1104, 1108–09 (1996). In the context of MDA preemption,

> Once the FDA approves a device, the manufacturer is required to report any information that reasonably suggests that the device (1) "[m]ay have caused or contributed to a death or serious injury" or (2) "[h]as malfunctioned" and that any recurring malfunction "would be likely to cause or contribute to a death or serious injury."

Stengel, 704 F.3d at 1226–27 (citing 21 C.F.R. § 803.50(a)). In line with Riegel, the Ninth Circuit en banc panel in Stengel held that to the extent the state-law duty parallels a federal-law duty under the MDA, the state law failure-to-warn claim is not expressly or impliedly preempted by the FDA. Id. at 1233. The concurring opinion in Stengel, which is joined by seven other judges, noted that the plaintiffs' failure-to-warn claim was not expressly preempted because they alleged that defendant failed to report adverse events to *the FDA itself*, which is a requirement not "different from, or in addition to" the requirements imposed by federal law. 704 F.3d at 1234 (citing 21 C.F.R. § 803.50(a)) (Watford, J., concurring). The concurrence explained that "had the plaintiffs predicated their claim on a failure to warn doctors directly—an action not required by FDA regulations—that claim would have been preempted because it would have been an addition to the federal requirement." Perez, 711 F.3d at 1118 (citing Stengel, 704 F.3d at 1234 (Watford, J., concurring)).

Seedman's claim is premised on CAM's failure to warn the FDA, not CAM's failure to warn himself, members of the general public, or physicians. (See Compl. ¶ 103.) Thus, under Stengel, Seedman's third claim is not preempted. Moreover, any supposed lack of factual detail concerning this claim is of no concern because "little factual detail is necessary or available when a plaintiff is alleging that the defendant failed to act." Thibodeau, 2014 WL 3700868, at *4 ("The Court finds Plaintiff's failure-to-warn-the-FDA claim to be sufficiently pled to defeat preemption.").

d. *Fourth Claim: Negligence*

Seedman's negligence claim alleges that CAM breached its duty to follow the PMA, CGMP, and federal requirements in the "design, formulation, testing, quality assurance, quality control, labeling, manufacture, marketing, promotion, sale and/or distribution of the Cochlear Implant into the stream of commerce." (Compl. ¶ 109.) In Riegel, the Supreme Court affirmed the dismissal of, among other claims, "negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the" medical device at issue. Riegel, 552 U.S. at 321, 335. Even so, nearly all of the bases for Seedman's negligence claim are identical those that the Supreme Court declared that § 360k preempted. The only bases alleged by Seedman that the Supreme Court did not specifically address as being preempted are: (1) formulation; (2) manufacture; (3) quality

assurance; (4) quality control; and (5) promotion. Compare id. with (Compl. ¶ 109.) However, formulation appears identical to design and testing; quality assurance and quality control appear identical to inspection; and promotion appears identical to marketing. Seedman cannot plead around Riegel by using different words for the same type of behavior.[5]

Thus, the only remaining basis for his negligence claim is CAM's manufacturing of the cochlear implant. Neither party identifies it as such, but this is essentially a negligence per se claim because Seedman alleges that CAM failed to use reasonable care in the manufacturing of the cochlear implant that parallels the federal requirements. (See Compl. ¶¶ 109, 114.) In California, a presumption of negligence is established if the defendant (1) violates a statute, ordinance, or regulation of a public entity; (2) the violation proximately caused death or injury to person or property; (3) the death or injury resulted from an occurrence of the nature which the statute, ordinance, or regulation was designed to prevent; and (4) the person suffering the death or injury was one of the class of persons for whose the statute, ordinance, or regulation was adopted. Cal. Evid. Code. § 669(a). Seedman pleads sufficient facts to meet these elements. (See Compl. ¶¶ 72–85 (establishing the first, third, and fourth elements), 109–10 (same), 114 (same), 117 (establishing the second element).)

Additionally, this negligence per se claim is not impliedly preempted by Buckman, which held that "fraud-on-the-FDA" claims were impliedly preempted. 531 U.S. at 349–50. Buckman does not apply here because Plaintiffs do not allege a "fraud-on-the-FDA" claim, but a traditional state law products liability claim. The distinction is significant because here, Seedman's allegations are not based on any fraudulent conduct on the part of CAM in front of the FDA, but based on CAM's "alleged failure to use reasonable care in the production of the product" that parallels requirements under the federal regulations. See id. at 352–53; see also Lohr, 518 U.S. at 481 (common law negligence action as opposed to fraud claim based on FDCA disclosure requirements); Perez, 711 F.3d at 1119 (recognizing the distinction between "fraud-on-the-FDA" claim

[5] This conclusion applies to Seedman's additional allegation in paragraph 111 regarding the "advertising and sale of the Cochlear Implant," and the allegation in paragraph 113 regarding the "labeling of the Cochlear Implant" and issuing pre-marketing or post-marketing warnings. (See Compl. ¶¶ 111, 113.)

and manufacturing defect claims in Lohr).

Therefore, Seedman's claim survives only to the extent that it alleges negligence per se based on CAM's alleged failure to follow federal requirements in the manufacturing of the cochlear implant.

e. *Fifth Claim: Negligent Misrepresentation*

Similar to his strict liability failure to warn claim, this claim alleges that CAM failed to report to the FDA the "increasing number of hermeticity failures with the . . . cochlear implants that causes or contributed to serious injury." (Compl. ¶ 120.) In contrast to the failure to warn claim, however, this claim alleges a misrepresentation to the FDA based on a duty of care CAM owed to Seedman. (Id. at ¶¶ 122–23.) Stengel warned that "any attempt to predicate [a] claim on an alleged state law duty to warn doctors directly would have been expressly preempted under 21 U.S.C. § 360k." Stengel, 704 F.3d at 1234 (Watford, J., concurring). This preemption extends to allegations involving a duty to the public because such a duty "is not imposed by federal law, and the state law claim would therefore impose a duty different from or in addition to those imposed by the FDCA . . . ." Thibodeau, 2014 WL 3700868, at *4. Because Seedman's claim is premised on a duty CAM allegedly owes to Seedman and such a duty would add to federal requirements, this claim is preempted by § 360k.

f. *Sixth Claim: Breach of Express Warranty*

Thibodeau noted that "[c]laims for breach of express and implied warranties are widely held to be preempted." 2014 WL 3700868, at *5. With respect to Seedman's express warranty claim, it is preempted by the MDA because the representations CAM may make with respect to the cochlear device are limited to those approved by the FDA. Id. (quoting Kitchen v. Biomet, Inc., No. 13–18–HRW, 2014 WL 694226, at *6–7 (E.D. Ky., Feb. 21, 2014)). Thus, a state-law express warranty claim would be "different from, or in addition to" the FDA's requirements. Riegel, 552 U.S. at 321–22.

g. *Seventh Claim: Breach of Implied Warranty of Merchantability*

Riegel affirmed dismissal of a breach of implied warranty claim because it was

preempted by § 360k. Riegel, 552 U.S. at 320, 335. Seedman does not address why Riegel does not foreclose this claim. Thus, § 360k preempts his seventh claim.

C. Conclusion

For the foregoing reasons, the Court dismisses with prejudice Seedman's second, fifth, sixth, and seventh claims. However, Seedman's first and third claims survive. His fourth claim also survives, but only to the extent that it relies on the allegations asserting negligence per se based on a manufacturing defect. The remainder of Seedman's fourth claim is dismissed with prejudice.

IV. CONCLUSION

For the foregoing reasons, CLTD's motion to dismiss is STAYED for forty-five (45) days pending completion of jurisdictional discovery relating to CLTD's relationship with CAM. As discussed at oral argument, Seedman may conduct a one-day FRCP 30(b)(6) deposition of York or the person that CLTD designates as most knowledgeable.

CAM's motion to dismiss is GRANTED IN PART and DENIED IN PART.

IT IS SO ORDERED.

: 30

Initials of Preparer kjt